

## **Request for Expression of Interest**

### **EVIDENCE SYNTHESIS FOR THE USE OF STEM CELL THERAPY: CONDUCTING SYSTEMATIC REVIEWS/META-ANALYSES**

#### **BACKGROUND:**

1. A new process has been established in the Ministry of Health & Family Welfare wherein one comprehensive evidence-based guidelines will be jointly developed by DoHFW, DGHS and DHR using a rigorous and robust scientific process.
2. The generation of such evidence will include collation of systematic reviews and meta-analysis of existing literature on well-defined review questions. The evidence obtained from SR & MA will be graded for its strength using the GRADE (Grading of Recommendations Assessment Development & Evaluation) Approach. This grading will be done to assess the quality of evidence which will be followed by formulation of recommendations after the application of Evidence to Decision (EtD) framework.
3. In this regard, EoI is invited from interested researchers for doing systematic reviews and meta-analysis. The applicants will be expected to synthesize and gather evidence on the identified review questions (PICO) and grade the quality of evidence.

#### **SCOPE OF WORK:**

Stem cell therapy is a novel therapeutic approach that utilizes the unique properties of self-renewal and differentiation of stem cells, to regenerate or replace damaged cells and tissues in the human body. Stem cell therapy is lately being offered as a potential solution for a variety of incurable & debilitating diseases. It is quintessential to take an evidence-based approach during the development of these regenerative therapies, with the best quality evidence being sought to determine the true effectiveness & efficacy of such approaches.

The systematic review teams will be commissioned to conduct systematic reviews/ meta-analysis in the well-defined review questions formulated by the Guideline Development Group on the use of stem cell therapy in diseases/disorders.

ICMR invites researchers/academicians and scientists to express interest for conducting systematic reviews/meta-analysis for the generating evidence on the **Use of Stem Cell Therapy**. The tentative/indicative list of review questions for the same is provided below:

#### **Orthopedic Disorders:**

1. In patients with osteoarthritis, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
2. In patients with Tendinopathy, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

3. In patients with Avascular Necrosis, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
4. In patients with Cartilage defects, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
5. In patients with Meniscopathies, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
6. In patients with Non union of bone, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

**Neurological disorders:**

7. In patients with Multiple Sclerosis, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
8. In patients with Spinal Cord Injury, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
9. In patients with Amyotrophic Lateral Sclerosis, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
10. In patients with Stroke, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

**Ophthalmologic disorders:**

11. In patients with Retinitis pigmentosa, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
12. In patients with Corneal surface defects, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
13. In patients with Macular Degeneration, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

**Cardiac disorders:**

14. In patients with Myocardial Infarction, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
15. In patients with Dilated Cardiomyopathy, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

**Microvascular/Surgical disorders:**

16. In patients with Chronic Wounds, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
17. In patients with Critical Limb Ischemia, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

**Paediatric Disorders:**

18. In patients with Cerebral Palsy, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

19. In patients with Autism Spectrum Disorder, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
20. In patients with Osteogenesis imperfect, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
21. In patients with Bronchopulmonary dysplasia, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
22. In patients with Hypoxic Ischemic Encephalopathy, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
23. In patients with Muscular Dystrophy, what is the efficacy and safety of stem cell therapy as compared to the standard of care.
24. In patients with Spinal Muscular Atrophy, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

**Respiratory Disorders:**

25. In patients with Acute Respiratory Distress Syndrome, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

**Dermatologic Disorders:**

26. In patients with Skin rejuvenation, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

**Endocrinologic Disorders:**

27. In patients with Diabetes, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

**Gastroenterologic/ Hepatologic disorders:**

28. In patients with Liver Cirrhosis, what is the efficacy and safety of stem cell therapy as compared to the standard of care.

**WHO CAN APPLY:**

- The proposal to undertake the assignment can be submitted for financial support through ONLINE MODE ONLY on e-PMS portal by Scientist/Professional who has a regular employment in Medical Institutes/Research institutes/University/Government and Semi government organizations (documentary evidence of their recognition including DSIR certificate should be available).
- **Kindly note that as this is a highly time sensitive issue, it is desirable that the commissioned review be completed in stipulated time of 3 Months**

### **APPLICATION PROCESS:**

- The Applicant and his/her systematic review team should have demonstrable experience in conducting systematic review and at least 2 published systematic reviews as first/corresponding author in indexed journals in last 3 years in relevant subject areas mentioned above.
- The application received will go through a review process and the selected candidate will be notified on completion of the review process.

### **DELIVERABLES:**

- Technical protocol for conducting systematic reviews and meta-analyses, including search strategy, inclusion/exclusion criteria, plan for evidence quality (certainty) assessment and statistical analysis plan.
- Monthly review by the expert group meeting (and participation in any pre-meetings or online webinars).
- A GRADEpro summary of evidence profiles complete with ratings of the certainty of evidence.
- A database of studies included in the systematic reviews
- Finalized report and co-authored paper for publication.

### **BUDGET:**

1. Financial Support upto Rs. 7.00 Lacs will be provided to all non-ICMR Institutes.
2. ICMR institutes may take support from intramural funding.
3. Budget should not exceed above Rs.7.00 lakh/ 3 months.
4. Justification under all subheadings needs to be indicated.

### **TIMELINE:**

<b>Activities</b>	<b>Date</b>
Release of Call	25 <sup>th</sup> July 2023
Last Date for submission of proposal	11 <sup>th</sup> August 2023
Review and Selection	25 <sup>th</sup> August 2023
Date of completion of commissioned review assigned to the selected team	3 month from the date of Start

### **Important note for the submission of proposal:**

1. Before proceeding to submit the proposal, it is suggested to read user manual and ICMR Extramural
2. Research Program guidelines; and make ready all relevant information, documents and research plan

3. (<https://epms.icmr.org.in>). Open the ICMR Electronics Project Management System (e-PMS) portal <https://epms.icmr.org.in>.
4. The user manual of e-PMS (under Guidelines → e-PMS manual) is available at the portal.
5. Project proposal submission is three steps process in e-PMS:
  - Step 1: PI registration/ Login (<https://epms.icmr.org.in/userLogin>)
  - Step 2: Verify email ID and complete/ update PI profile
  - Step 3: Proposal submission
6. After completing mandatory section of PI profile, click on “Proposal submission →Click on Submit new proposal → Select the program from drop-down box as " Evidence Synthesis for the Use Of Stem Cell Therapy: Conducting Systematic Reviews/Meta-Analyses Proposals” →Fill the form step by step.

**For any queries related to the call, please contact**

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